

**Remarks and Arguments**

Claims 1-28 are pending in the application. Claim 1 has been amended.

**Rejections Under 35 U.S.C. § 102**

**Malenchek**

Claims 1-8, 12-19, 21-23, and 27-28 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,980,494 ("Malenchek"). Applicants respectfully traverse this rejection as follows.

Malenchek discloses a safety syringe 2 and a thermoplastic molded housing 4, a thermoplastic molded vial 8, a thermoplastic camming vial positioning ring 10 secured to vial 8 while being rotatably and axially movable. (*Malenchek* at col. 2, ll. 60-66.) A needle assembly 36 is secured to vial 8. (*Id.* at col. 2, l. 67.) The outer peripheral surface of vial 8 is molded integral with a circular cylindrical ratchet member 100 including three annular equally spaced camming tabs 102. (*Id.* at col. 4, ll. 10-15.) Ratchet teeth 112 are disposed between adjacent tabs 102, all equally spaced about the vial 8 peripheral surface. (*Id.* at col. 4, ll. 20-23.)

Ring 10 also includes a ring member 120 with three equally spaced camming tabs 122 for engaging the tabs 102 and teeth 112 of vial 8. (*Id.* at col. 4, ll. 36-47.)

In use, the syringe 2 has the vial 8 initially in a retracted position, as shown in FIG. 1a, in which the needle assembly 36 is fully enclosed by the housing 4. (*Id.* at col. 4, l. 64 to col. 5, l. 3.) Vial 8 is secured to the housing by ratchet member 100 and flange member 90 (see, e.g., FIG. 2). In this position, tabs 122 of ring 10 abut with and mate with tabs 102 of vial 8. (*Id.* at col. 5, ll. 7-14.)

For the sole purpose of expediting prosecution, sole independent claim 1 has been amended to recite a "syringe body wholly contained and retained within the syringe casing" even during syringe operation. Support for this amendment can be found in the specification at p. 6, ll. 21-32, which states that an elongate syringe body 3 is located within a casing 2 that is at least substantially closed at each end 7, and 8

except for access openings 9 and 10. From FIG. 1, it can be seen that due to the small size of the access openings, the syringe casing 2 will wholly retain the syringe body 3 during the syringe operation. Accordingly, no new matter has been added.

By this arrangement, the syringe body of claim 1 is isolated from the user regardless of the position of the syringe. There is no need for a user to operate both the body and plunger during use. In contrast, Malenchek's syringe has the vial 8 only partially shielded within the housing 4 when in the retracted position. A user of the syringe has to be mindful of both the exposed vial and the plunger when in operation.

It is further noted that the projection of the syringe of Malenchek is always engaged with the track even in the final "locked position" shown in Figure 22. Accordingly, in the arrangement disclosed in Malenchek, movement of the syringe body within the casing relative to the casing does not truly disable the syringe as is required by claim 1. On the contrary, the syringe is only tightly locked into the position on a track formed by teeth 112 of vial 8. As can be seen by examining the track configuration in FIGs. 14 to 22, it would be still possible for a user to move the exposed syringe body relative to the housing 4 to manipulate the camming tabs 122 of ring 10 through movement of, from the locked position along the track to move the camming tabs 122 backwards along the track to a position where the needle can be exposed.

Applicants respectfully submit that, Malenchek fails to describe or suggest the limitations recited in sole independent claim 1, and thus fails to anticipate any of the claims. Accordingly, Applicants respectfully request withdrawal of this rejection.

### **Malenchek 2**

Claims 9-11, 20, and 24-25, are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,926,697 ("Malenchek 2"). Applicants respectfully traverse this rejection.

Applicants respectfully submit that Malenchek 2 is not a proper reference under 35 U.S.C. § 102(e). Malenchek 2 has an earliest U.S. filing date of May 13, 2003. The present application claims priority to Australian Application No. 2003901382, a certified

copy of which was filed on the filing date of the present application. It is well settled law that 102(e) rejection can be overcome by "applicant's earlier foreign priority application" if the earlier application supports the claims of the application at issue. (M.P.E.P. § 2136.05, *In re Gosteli*, 872 F.2d 1008, 1010 (Fed. Cir. 1989).

Priority Australian Application No. 2003901382 was filed on March 25, 2003, which occurs before the earliest filing date of Malenchek 2, and supports each of the limitations of the rejected claims at issue. It is also noted that each of the figures in Australian Application No. 2003901382 is essentially identical to those of the present application.

Notwithstanding the improper use of Malenchek 2 as an anticipatory reference, Applicants also respectfully submit that Malenchek 2 fails to disclose or teach a "syringe body wholly contained and retained within the syringe casing" during syringe operation, for the reasons cited above against Malenchek.

Because Malenchek 2 is not a proper reference under 35 U.S.C. § 102(e), Applicants respectfully request withdrawal of this rejection.

### **Rejection Under 35 U.S.C. § 103**

Claim 26 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Malenchek in view of U.S. Patent No. 5,085,640 ("Gibbs"). The Examiner relies on Gibbs for allegedly teaching an access hole offset from the needle at FIG. 42. Applicants respectfully traverse this rejection.

As discussed above, Malenchek fails to teach or suggest a "syringe body wholly contained and retained within the syringe casing" during syringe operation. Gibbs fails to remedy this deficiency, and at best, fails to teach a syringe casing separate from the syringe body, as claimed. At FIG. 42, cited by the Examiner, and the preceding figures (e.g., FIGs. 38-41), it can be seen that even if the blood collection tube 217 (col. 11, l. 32) is asserted to be a syringe body, it is not wholly contained within the syringe housing during operation of the syringe. Moreover, there is no plunger that is used in this embodiment, as the blood collection tube withdraws fluid from a patient.

Accordingly, Applicants respectfully submit that a *prima facie* case of obviousness has not been established, and respectfully request withdrawal of this rejection.

### CONCLUSION

Reconsideration of the present application and withdrawal of the Section 102 and 103 rejections is respectfully requested. If the examiner believes that a teleconference would expedite prosecution of the present application, the examiner is invited to call the Applicants' undersigned attorney at the Examiner's earliest convenience.

Any amendments or cancellation of claims, drawings, specification or the like made herein is made without prejudice and is not an admission that said canceled or amended subject matter is not patentable or included within the scope of the claims as amended. Applicant reserves the right to pursue said canceled or amended subject matter in one or more continuing, divisional or other applications.

The examiner is hereby authorized to charge any fees required in addition to the fees submitted herewith or direct any payment under 37 C.F.R. 1.17, 1.16 to Deposit Account number 02-3038.

Respectfully submitted

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